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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

RECKITT BENCKISER LLC and UCB MANUFACTURING, INC. Plaintiffs, v. AMNEAL PHARMACEUTICALS, LLC Defendant.	Civil Action No.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Reckitt Benckiser LLC and UCB Manufacturing, Inc. (hereinafter, collectively, "Plaintiffs"), for their Complaint herein against defendant Amneal Pharmaceuticals, LLC (hereinafter, "Defendant") allege as follows:

NATURE OF ACTION

1. This is an action for patent infringement.

PARTIES

2. Plaintiff Reckitt Benckiser LLC is a limited liability company organized and existing under the laws of the State of Delaware, having its principal place of business at 399 Interpace Parkway, Parsippany, New Jersey 07054.

3. Plaintiff UCB Manufacturing, Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 755 Jefferson Road, Rochester, NY 14623.

4. On information and belief, Defendant Amneal Pharmaceuticals, LLC ("Amneal") is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 440 US Highway 22 East, Suite 104, Bridgewater, New Jersey 08807.

JURISDICTION AND VENUE

5. This action arises under the patent laws of the United States of America. This Court has original jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

6. On information and belief, Amneal is engaged in, among other things, the research and development of pharmaceutical liquids and solids and the manufacturing of pharmaceutical products for licensing and sale throughout the world, including the United States and New Jersey.

7. Based on the facts and causes alleged herein, this Court has personal jurisdiction over Amneal.

8. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 (b) and (c), and 28 U.S.C. § 1400(b).

CLAIM FOR RELIEF - PATENT INFRINGEMENT

9. Plaintiff Reckitt Benckiser LLC holds an approved new drug application ("NDA") NDA No. 18-658 for Delsym® extended release liquid suspension, which contains the active ingredient dextromethorphan polistirex (equivalent to 30 mg of dextromethorphan hydrobromide per 5 mL) (hereinafter "Delsym®"). Delsym® has been approved by the United States Food and Drug Administration ("FDA") to temporarily relieve cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants.

10. Plaintiff Reckitt Benckiser LLC is the exclusive licensee of United States Letters Patent No. 5,980,882 ("the '882 patent"). The '882 patent was duly and legally issued on November 9, 1999.

11. The '882 patent claims certain pharmaceutical compositions using a drug-resin complex and a chelating agent and certain methods of making these pharmaceutical compositions. The claims of the '882 patent include Delsym® and its method of production. A true copy of the '882 patent is attached hereto as Exhibit A.

12. The '882 patent originally was assigned by its inventor, Martin L. Eichman, to Medeva Pharmaceuticals Manufacturing, Inc. UCB S.A. and UCB, Inc. (a wholly-owned subsidiary of UCB S.A.) subsequently acquired the successor-in-interest to Medeva Pharmaceuticals Manufacturing, Inc., including all of its rights under the '882 patent. The successor-in-interest to Medeva Pharmaceuticals Manufacturing, Inc. was renamed "UCB Manufacturing, Inc.," a plaintiff in this action. UCB, Inc. and UCB Manufacturing, Inc. then licensed their rights under the '882 patent to Adams Respiratory Operations Sub, Inc. and its

parent company, Adams Respiratory Therapeutics, Inc., (collectively, "Adams") in June, 2006. Reckitt Benckiser Inc. acquired Adams in or about January of 2008, including all of its rights under the '882 patent. On January 1, 2011 Reckitt Benckiser Inc. was reorganized into a limited liability company under the original filling and changed its name to Reckitt Benckiser LLC, Plaintiff.

13. Amneal submitted to the FDA an abbreviated new drug application ("ANDA"), namely ANDA No. 203133, under the provisions of 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, and sale of dextromethorphan polistirex extended release suspension, equivalent to 30 mg of dextromethorphan hydrobromide per 5 mL (hereinafter "Amneal's product").

14. By filing its ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Amneal's product before the expiration of the '882 patent, Amneal has committed an act of infringement under 35 U.S.C. § 271(e)(2). Further, the commercial manufacture, use, offer for sale, sale and/or importation of Amneal's product will also infringe one or more claims of the '882 patent.

15. Amneal's method of manufacturing Amneal's product will infringe the '882 patent, either literally or under the doctrine of equivalents, violating 35 U.S.C. § 271(a). This will occur at Amneal's active behest, and with its specific intent, knowledge and encouragement. On information and belief, Amneal will actively induce, encourage, aid and abet this administration with the knowledge that it is in contravention of Plaintiffs' rights under the '882 patent.

16. Amneal made, and included in its ANDA, a certification under 21 U.S.C. § 355(j)(2)(vii)(IV) ("Paragraph IV certification") that, in its opinion, claims 6, 15, 17, 18, 20, 21, 29, 30-33, 35 and 37 of the '882 patent will not be infringed by Amneal's product.

17. Amneal made, and included in its ANDA, a Paragraph IV certification that, in its opinion, claims 1-5, 7-14, 16, 19, 22-28, 34, and 36 of the '882 patent are invalid.

18. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of any approval of the aforementioned ANDA relating to Amneal's product be a date which is not earlier than the later of the April 16, 2017 expiration date of the '882 patent or any later date of exclusivity to which Plaintiffs are or become entitled. Further, Plaintiffs are entitled to an award of damages for any commercial sale or use of Amneal's product, and any act committed by Amneal with respect to the subject matter claimed in the '882 patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

19. On information and belief, when Amneal filed its ANDA, it was aware of the '882 patent and that the filing of its ANDA with the request for its approval prior to the expiration of the '882 patent was an act of infringement.

20. A notice of Paragraph IV certification ("Notice Letter") must "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." 21 U.S.C. § 355(j)(2)(B)(iv)(II). The FDA's Rules and Regulations further require that the detailed statement include "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." 21 C.F.R. § 314.95(c)(6)(ii).

21. On or about September 27, 2011, Amneal sent a Notice Letter to Plaintiffs purporting to comply with the provisions of 21 U.S.C. § 355(j)(2)(B)(iv)(II) and the FDA regulations relating thereto.

22. Amneal has failed to comply with the statutory provisions set forth in paragraph 20 above. The opinions set forth in the Notice Letter that the '882 patent is not infringed and is invalid due to obviousness and other potential, unnamed theories are devoid of an objective, good faith basis in either the facts or the law. Amneal's Paragraph IV certification is a wholly unjustified infringement of the '882 patent.

23. Amneal has violated its duty of due care to avoid the known rights of the '882 patent.

24. This is an exceptional case, and Plaintiffs are entitled to an award of reasonable attorneys fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. Judgment that Amneal has infringed one or more claims of the '882 patent by filing the aforesaid ANDA relating to Amneal's product;

B. A permanent injunction restraining and enjoining Amneal and its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of Amneal's product;

C. An Order that the effective date of any approval of the aforementioned ANDA relating to Amneal's product be a date which is not earlier than the later of the expiration

of the right of exclusivity under the ’882 patent, or any later right of exclusivity to which Plaintiffs are or become entitled;

D. Damages from Amneal for any commercial activity constituting infringement of the ‘882 patent;

E. A finding that this is an exceptional case under 35 U.S.C. § 285, and that Plaintiffs are entitled to the costs and reasonable attorney fees in this action; and

F. Such other and further relief as the Court may deem just and proper.

Dated: November 9, 2011

s/John E. Flaherty
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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Plaintiffs, by their undersigned counsel, hereby certify pursuant to L. Civ. R. 11.2 that the matter in controversy is the subject of RECKITT BENCKISER INC. and UCB MANUFACTURING, INC. v. TRIS PHARMA, INC. and YU-HSING TU, Civil Action 3:09-cv-03125-FLW-DEA (D.N.J.).

Dated: November 9, 2011

Respectfully submitted,

s/John E. Flaherty
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